RESEARCH ADVISORY PANEL OF CALIFORNIA

MEETING MINUTES

October 10, 2025 at 1:00 pm (Pacific)

OPEN SESSION

1. Call to Order, Establishment of a Quorum, and General Announcements

Panel Members Present: Boris Heifets, Daniele Piomelli, James Gasper, Jennifer Mitchell, Kelly Lee, and Martine D'Agostino.

Panel Members absent: None

A quorum was established

Staff Present: Tanveer Khan, Executive Officer

Chairperson Jennifer Mitchell returned after Agenda Item 3 to general announcements to announce that that due to recent funding cuts, RAPC has lost Panel Member Cyrus Rangan and RAPC is working with CDPH to find a replacement. In the meantime, she reminded Panel Members of the importance of ensuring RAPC can establish a quorum.

2. Approval of Panel Meeting Minutes – August 15, 2025

Chairperson Mitchell asked everyone to take a look at last meeting's minutes and asked about any changes. Hearing none, she asked for a motion to approve the minutes.

Panel Member Boris Heifets moved to approve the minutes, and Panel Member James Gasper seconded them. Chairperson Mitchell asked if there was anyone not in favor, and not hearing any objections, she announced the minutes stood approved.

3. RAPC as an Authorized Entity

Chairperson Mitchell summarized that Agnes Balla from the UC Office of the President had some concerns about the language that RAPC was using in some of the consent forms and had asked to revisit the language. Chairperson Mitchell said she hoped Panel Member Martine D'Agostino could give some guidance from her perspective as a lawyer because it was unclear to

the Panel what the legislative language actually meant for RAPC's ability to review certain types of records. Chairperson Mitchell then asked Panel Member D'Agostino if she had a chance to look into that any further.

Panel Member D'Agostino recalled that RAPC had a discussion at a prior Panel meeting about whether the consent form needed to specifically call out RAPC to receive HIPAA-protected material, and whether RAPC would actually need to receive HIPAA-protected material. Panel Member D'Agostino said she did not have anything new to add to the conversation except related to a point that was made that DOJ would probably investigate any malfeasance by a study that might require HIPAA-protected material. She said the DOJ cannot be relied on to initiate any kind of particular investigation, that it is super discretionary, and so any AG can make a call about whether they are going to investigate an issue like that, so she did not think RAPC should rely on the DOJ's investigative authority when they decide that RAPC might not need to access HIPAA-protected material to investigate some kind of problem with the study.

Chairperson Mitchell agreed that made sense and asked the Panel to think about if someone brought RAPC an issue that they believed should be investigated. She gave an example if a study was recruiting participants that should have been excluded from the study, and that resulted in an adverse effect, and RAPC was asked to weigh in. Chairperson Mitchell asked the Panel what they would do and whether they would need to look at those medical records themselves.

Panel Member Heifets ventured that they would refer it to the FDA, who should be conducting the site inspections, reviewing the master files and all of the adverse event reports.

Chairperson Mitchell liked that approach and asked if anyone had an issue with that.

Panel Member James Gasper clarified that it applied if it was an FDA-approved drug.

Chairperson Mitchell asked the Panel Members what they should do if the drug wasn't FDA-approved.

Panel Member Heifets suggested it would be clear if the drug had undergone an IND; however, for drugs that didn't require an IND, they would require IRB approval, and they would still have to report adverse events to the FDA. He said for a severe event none of that changes.

Chairperson Mitchell asked whether that would give FDA the purview to take a look and open medical records.

Panel member Gasper asked whether those were just MedWatch reports.

Panel member Heifets questioned if that would be whomever would be administering the trial, and felt there were half a dozen other entities that would have priority. He gave an example of

an allergy that was missed and the subject had an allergic reaction and suggested that there were others such as the ME, the IRB and legal, and that it would go through all of those processes to get resolved. Panel Member Heifets also gave a hypothetical scenario: A complaint came through the DOJ about a trial that RAPC reviewed and RAPC found the application to be complete.

Panel Member Daniele Piomelli asked whether RAPC would look into cases of diversion in animal and non-human research.

Chairperson Mitchell said the previous Chairperson believed that RAPC should look into it, that there were complaints raised in the past and that was the previous Chairperson's assumption as an attorney and a member of the California Department of Justice. She asked the Panel whether as a committee they agree that there's probably no reason for RAPC to be listed on the HIPAA waiver, or whether there were other comments or thoughts prior to moving to a vote.

Panel member Kelly Lee suggested if policies did not exist already, that there should be something in the way that they approve the applications to make sure there are governing bodies that would handle issues such as diversion, misuse, and theft. She said adverse events are covered by the IRB for human subjects, also adverse event reporting, surveillance, and all of that. Panel Member Lee questioned whether all of the application processes had all of those things accounted for.

Chairperson Mitchell agreed that was the thing to do. She gave an example of a study from outside the U.S. that wanted to bring controlled substances into the U.S. and use a facility in California to run its experiments and how it couldn't be determined how it would be adjudicated if something went wrong.

Panel Member Heifets suggested it would be the DEA if there's diversion and questioned how it would ever be RAPC with the responsibility to investigate and not some other branch of DOJ.

Panel Member Lee agreed that RAPC should not be the one investigating. However, she felt RAPC needed to make sure there was someone listed who would and that the public knew who to contact.

Panel Member Piomelli discussed the feasibility of RAPC having the time and manpower to conduct an investigation and the different state and federal level agencies already in place.

Panel Member Gasper questioned if the issue was about study design, implementation, and monitoring. He felt that would fall under RAPC purview and that could involve exposure to identifiable information into the way a study is conducted.

Chairperson Mitchell gave an example of a whistleblower complaint that a study wasn't randomizing subjects appropriately and suggested that would fit with Panel Member Gasper's comment.

Panel Member Gasper agreed that it opened the door to an area where RAPC may be the only responsible entity.

Panel Member Heifets asked Panel Member D'Agostino to weigh in on things like trial misconduct, design, or breach because he was really struggling to think of something where RAPC would be the only one to have reviewed something.

Executive Officer Khan asked Panel Members to consider if a RAPC-approved study had a very obvious problem with the study design such as a missing drug interaction or exclusion criteria.

Panel Member Heifets said that would be something the IRB would have signed off on.

Panel Member D'Agostino questioned whether RAPC had the resources to conduct the kind of investigation that would be required here.

Chairperson Mitchell raised concerns about the budget to conduct a true investigation.

Panel Member D'Agostino suggested the solution was not to figure out how RAPC could logistically perform an investigation if it had to, but to memorialize a decision to report incidents like that to the DOJ and what would go into that report and who would need to sign off on it and what documentation would be needed because then they would have done their duty.

Chairperson Mitchell liked the idea and suggested if the other Panel Members felt comfortable with that, someone could make a motion that RAPC would memorialize that they would report such an incident to DOJ. She said she didn't know what the proper channel would be, but that maybe they could come up with some sort of reporting form.

Panel Member D'Agostino wasn't sure what the proper channel would be but said that a complaint could be filed on the DOJ's website, but she wasn't sure what division in the office would handle it.

Chairperson Mitchell suggested they could find out and could potentially include that information on the RAPC website and say that in the case of a complaint the information would be referred to that department in DOJ.

Panel Member Lee made the motion to accept that RAPC would report incidents to the DOJ.

Panel Member Heifets seconded the motion.

Chairperson Mitchel asked for a vote on creating a process by which complaints would be referred to the DOJ for processing.

Vote on creating a process by which complaints would be referred to the DOJ for processing.

Boris Heifets - Yes

Daniele Piomelli -Yes

Kelly Lee - Yes

James Gasper - Yes

Jennifer Mitchell - Yes

Martine D'Agostino - Yes

Public Comment

None.

4. 2026 Panel Meeting Dates

Chairperson Mitchell asked Executive Officer Khan to lead the discussion on the selection of Panel meeting dates.

Executive Officer Khan proposed a Friday schedule with Panel meetings held on the second Friday of every other month. She asked whether the Panel would like to discuss alternative dates and times.

Chairperson Mitchell asked, given the current size of the Panel, how many members RAPC is allowed to be down in order to still meet quorum.

Executive Officer Khan replied that the Panel could only be down one more member. RAPC would need a majority, which would be five out of the eight seats.

Chairperson Mitchell asked to confirm whether the number is out of the full number of seats on the Panel or the number of sitting members and whether there is any way to receive a waiver given the number of empty seats on the Panel.

Panel Member D'Agostino confirmed it was her understanding that it was the total number of seats and she didn't think so in the case of a waiver, because that would allow smaller and smaller groups to make important decisions.

Chairperson Mitchell asked whether the dates proposed by Executive Officer Khan caused any problems for anyone.

Panel members clarified the dates and times, looked at their calendars, and discussed their potential availability and the challenges of scheduling so far in advance.

Executive Officer suggested posting the Friday schedule, and the Panel could revisit any specific dates or times at the next meeting.

Chairperson Mitchell asked if there were any dissenters to the tentative schedule, and hearing none, prepared to move on.

Executive Officer Khan asked for confirmation whether the Panel wanted to revisit the schedule at the December meeting.

Chairperson Mitchell said it would only be revisited if any of the Panel members, after looking further at their calendars, came to the Executive officer and wanted to revisit it again.

Public comment

None.

5. AB 1103 and SB 470

Chairperson Mitchell explained that SB 470 was signed and both bills could potentially be signed by the Governor before next week. She indicated there was not much more to share until they knew the second bill was signed. Chairperson Mitchell explained the first bill was related to remote meetings, and the second bill was about the updated RAPC language and processes for expedited review. She asked the Panel members if they had any questions about the two bills, and hearing none, moved on.

Public Comment

None.

CLOSED SESSION

Chairperson Mitchell and Panel Members Heifets, D'Agostino, Gasper, Lee and Piomelli entered closed session under Government Code Section 11126, subd. (c)(20).

OPEN SESSION

Panel members reentered the open session and roll call was taken. Panel Members present: Jennifer Mitchell, Boris Heifets, Martine D'Agostino, James Gasper, Kelly Lee and Daniele Piomelli.

Panel members absent: None.

A quorum was established.

The next meeting date was announced as Friday, December 12, 2025 and the meeting was adjourned.